

FEBRUARY 7, 2008

MICHAEL W. DOBBINS
CLERK, U.S. DISTRICT COURT

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

NYCOMED GmbH and WYETH

Plaintiffs,

v.

APOTEX Inc. and APOTEX Corp.

Defendants.

CIVIL ACTION NO. _____

08 C 827

**JUDGE SHADUR
MAGISTRATE JUDGE NOLAN**

COMPLAINT FOR PATENT INFRINGEMENT

1. Nycomed GmbH is a corporation incorporated and existing under the laws of Germany, having its principal place of business at Byk-Gulden-Str. 2, 78467 Konstanz, Germany.

2. Wyeth is a Delaware corporation with offices at Five Giralta Farms, Madison, NJ 07940.

3. Nycomed GmbH is at times referred to hereinafter as "Nycomed."

4. Upon information and belief, Defendant Apotex Inc. is a corporation incorporated and existing under the laws of Canada and having a principal place of business at 380 Elgin Mills Road East, Richmond Hill, Ontario, Canada L4C 5H.

5. Upon information and belief, Defendant Apotex Corp. is a Delaware corporation having a principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

6. Upon information and belief, Apotex Corp. is the U.S. subsidiary of Apotex Inc.

7. Apotex Inc. and Apotex Corp. are at times referred to hereinafter collectively as “Apotex.”

JURISDICTION AND VENUE

8. This action arises under the patent laws of the United States of America and jurisdiction exists under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391(c), 1391(d), and 1400(b).

9. Apotex has designated William A. Rakoczy of Rakoczy Molino Mazzochi Siwik LLP, 6 West Hubbard Street, Suite 500, Chicago, Illinois 60610, as Apotex’s agent authorized to accept service of process for Apotex in this action, and has thereby consented to personal jurisdiction in this district.

10. Upon information and belief, Apotex sells various products and does business throughout the United States including this district.

BACKGROUND FOR CLAIM FOR RELIEF UNDER 35 U.S.C. § 271 (e)(2)

11. Wyeth Pharmaceuticals Inc., a wholly-owned subsidiary of Wyeth, is the holder of New Drug Application (“NDA”) No. 20-988, by which the United States Food & Drug Administration (“USFDA”) granted approval for pantoprazole sodium injection 40mg, which is marketed and sold by the Plaintiffs in the United States under the trade name “[®]PROTONIX[®] I.V.”

12. Nycomed is the owner of United States Patent No. 6,780,881 B2 (“the ‘881 patent”), which was duly and legally issued on August 24, 2004, and which discloses and

claims certain pantoprazole preparations and injections. The sodium salt of pantoprazole is the active ingredient in PROTONIX® I.V.

13. Wyeth is the exclusive licensee of the '881 patent in the United States.
14. A copy of the '881 patent is attached as Exhibit A.
15. Upon information and belief, Apotex filed in the USFDA an Abbreviated New Drug Application ("ANDA"), including a certification with respect to the '881 patent under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355), seeking approval to manufacture, use or sell Pantoprazole Sodium Injectable, I.V. 40 mg, prior to expiration of the '881 patent.
16. Apotex's ANDA No. 79-197 lists pantoprazole sodium as the active ingredient in an injectable dosage form of the drug.
17. Upon information and belief, the Pantoprazole Sodium Injectable, I.V. 40 mg drug that is the subject of Apotex's ANDA will be manufactured by Apotex.
18. By letter dated December 21, 2007, Apotex sent a notice to Nycomed and Wyeth in which Apotex represented that it had filed an ANDA for Pantoprazole Sodium Injectable, I.V. 40 mg, including the certification with respect to the '881 patent, and that it sought approval of its ANDA prior to the expiration of that patent.
19. Nycomed received notice of the Apotex certification no earlier than December 24, 2007.
20. Wyeth received notice of the Apotex certification no earlier than January 2, 2008.

CLAIM FOR RELIEF UNDER 35 U.S.C. § 271(e)

21. Because Apotex seeks approval of its ANDA to engage in the commercial manufacture, use or sale of a drug claimed in the '881 patent before its expiration, Apotex has infringed the '881 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

22. Nycomed and Wyeth are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Apotex's ANDA be a date that is not earlier than the expiration date of the '881 patent, or any later expiration of exclusivity for the '881 patent to which Nycomed and/or Wyeth is or becomes entitled to.

23. Upon information and belief, Apotex was aware of the existence of the '881 patent and was aware that the filing of its ANDA and certification with respect to the '881 patent constituted an act of infringement of that patent.

24. Apotex's statement of the factual and legal bases for its opinion regarding non-infringement and invalidity of the '881 patent is devoid of an objective good faith basis in either the facts or the law.

25. This case is an exceptional one, and Nycomed and Wyeth are entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

26. Plaintiffs request that:

- a. Judgment be entered that Apotex has infringed the '881 patent by submitting the aforesaid ANDA;
- b. Judgment be entered that Apotex has infringed the '881 patent under 35 U.S.C. 271;

c. A permanent injunction be issued, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283, restraining and enjoining Apotex and its directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of preparations and injections as claimed in the '881 patent;

d. An order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 79-197 be a date that is not earlier than the expiration date for the '881 patent, or any later expiration of exclusivity for the '881 patent to which Plaintiffs are or become entitled; and

e. Judgment be entered that this is an exceptional case and that Plaintiffs are entitled to their reasonable attorney fees pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

f. For such other and further relief as the Court may deem just and proper under the circumstances.

Dated: February 7, 2008

/s/ Ericka K. Foster

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